

REMARKS

Claims 1-29 are pending in the application. Claims 1-14, 18-19, 21, 26, 27 and 29 have been amended. No new matter was added by this amendment. Claims 17, 25 and 28 has been canceled without prejudice to subsequent revival. The Applicants reserve their right to pursue the canceled claims in a divisional or continuation application. Entry of the amendment is respectfully requested.

Summary of Examiner Interview

The Applicants gratefully acknowledge the Examiner's courtesy in granting the Applicants' representatives a telephonic interview on October 15, 2007. The Examiner, the undersigned, and Peter J. Yim (Reg. No. 44,417) were the participants. Claim 1 was discussed. EP 0904729 was discussed. The general thrust of the discussion was Applicants' proposal to amend claims 1 and 19 to include the limitation that the suitable flow rate for the sensor is lower than the exhalation flow rate to distinguish the disclosure of a system for converting NO to NO₂ by increasing the pressure through the system in EP 0904729.

Rejections under 35 U.S.C. §112

Claims 2, 6-15, and 29 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite.

To the extent that the rejection applies to the claims as amended, the rejection is respectfully traversed.

With respect to claim 2, the Office Action indicates that it is unclear where flow regulator 6 is positioned in the device. The Office Action further states that "it would make more sense that the regulator is regulating the stored portion of the exhaled air." Claim 2 has been amended to clarify that the flow regulator is connected to the inlet and the buffer chamber, and to further clarify that the function of the flow regulator is to control the exhalation flow rate exhaled from the patient. The Examiner's attention is respectfully directed to paragraph [0025] of the specification, as published. As claimed and as described, flow regulator 6 serves to regulate the exhalation flow and in one embodiment, serves to further limit excess exhalation flow. Thus, the language of claim 2 is clear and definite in specifying that the flow regulator functions to control

exhalation flow. In light of this amendment, it is respectfully requested that the rejection of claim 2 under 35 U.S.C. §112, second paragraph, be withdrawn.

With respect to claim 6, the Examiner states that it is unclear what type of means is intended to verify the parameters and control exhalation. Claim 6 has been amended to refer to “control electronics.” Thus, it is respectfully requested that the rejection of claim 6 under 35 U.S.C. §112, second paragraph, be withdrawn.

With respect to claim 10, the Examiner states that it is unclear what type of structure is intended by “maze.” Claim 10 has been amended to recite that the buffer chamber is “formed as a long channel having a small cross-section.” Thus, it is respectfully requested that the rejection of claim 10 under 35 U.S.C. §112, second paragraph, be withdrawn.

With respect to claims 14 and 18, the Office Action indicates that the claims fail to specify that the smartcards comprise a computer readable medium. Claims 14 and 18 have been amended to specify that the smartcards comprise a computer readable medium. In light of this amendment, it is respectfully requested that the rejection of claims 14 and 18 under 35 U.S.C. §112, second paragraph, be withdrawn.

With respect to claim 15, the Examiner states it is not clear how the device is adapted to different users or different user groups. The Examiner suggests that clarification could be achieved by specifying that the smartcard comprises a computer readable medium. The Examiner’s suggestion is gratefully acknowledged. Claim 14, from which claim 15 depends, has been amended to specify that the smartcard comprises a computer readable medium. Hence, it is respectfully requested that the rejection of claim 15 under 35 U.S.C. §112, second paragraph, be withdrawn.

With respect to claim 17, the Office Action indicates that the claim appears to be a method of use claim. Claim 17 has been canceled without prejudice. Thus, the rejection under 35 U.S.C. §112, second paragraph, should be moot.

With respect to claim 26, the Examiner asserts that the claim allegedly fails to describe where the information is being entered. Claim 26 has been amended to specify that information is entered via a user interface. In light of this amendment, it is respectfully requested that the rejection of claim 26 under 35 U.S.C. §112, second paragraph, be withdrawn.

With respect to claim 29, the claim stands rejected under 35 U.S.C. §101 and §112, first paragraph, as allegedly lacking a well established utility. Claim 29 has been amended to specify a parameter and flow rate, and thus, provides an utility. Applicants respectfully request that the rejections of claim 29 under 35 U.S.C §101 and §112, first paragraph, be withdrawn.

The amendments have been entered to advance prosecution on the merits. However, the amendments must not be interpreted as acquiescence in the rejections.

Rejections under 35 U.S.C. §102

Claims 1-9, 11-12, and 17-19 stand rejected for allegedly being anticipated by EP 0904729 (herein the “EP publication”).

To the extent that the rejection applies to the claims as amended the rejection is respectfully traversed. Claim 17 has been canceled and claims 2-8, 11-12 and 18 depend directly or indirectly on amended claim 1. Claim 19 has also been amended.

Claims 1 and 19 have been amended to clarify that:

- a) a patient exhales at an exhalation flow rate;
- b) a flow regulator controls the exhalation flow rate;
- c) a sample of the exhaled air is stored in a buffer chamber;
- d) the sample is fed to an NO sensor from the buffer chamber at a flow rate suitable for the NO sensor; and
- e) the suitable flow rate for the NO sensor is lower the exhalation flow rate.

In comparison, the EP publication does not explicitly disclose controlling a flow rate (*i.e.*, controlling a flow rate to the measuring chamber (46)) which is due to the fact that the analyser disclosed in the EP publication is primarily focused on converting all of NO to NO₂ by *increasing the pressure* throughout the system. Specifically, the system increases the pressure in two stages. Herein, the Examiner is referred to Figure 2 which depicts two pumps (*i.e.*, pump 30 and pump 36) that successively compress the gas in order for the gas to enter the measuring chamber (46) where NO is converted to NO₂. This is supported in the specification in paragraph [0020] where it is disclosed that the pressurising means can be one or a plurality of pumps, connected in series, which

successively compress the gas in one or more stages. This is further supported in paragraph [0027] which teaches that the volume of the second pump (36) is much smaller than the volume of the first pump (30), so that the gas sample is compressed when it fills the second reciprocating pump (36). The ratio between the volumes is selected according to the pressure increase desired and the positive pressure available in the first control gas line (32). The large difference in volume causes a large pressure differential and, thus, more rapid conversion of NO into NO₂. Finally, compression of the gas sample increases the rate of reaction in the chemical reaction of NO and O₂, and virtually all the NO in the gas sample is converted into NO₂. In summary, the EP analyzer is based on successively increasing pressure and, thus, the flow rate coming into the measuring chamber (46) is likely higher than the flow rate coming into the analyzer (10).

In light of the amendments to claims 1 and 19 and the arguments presented above, it is respectfully requested that the rejection of claims 1-9, 11-12, and 17-19 under §102(b) be withdrawn.

Rejections under 35 U.S.C. §103

Claims 10, 22-23 and 25 are rejected as allegedly being obvious over EP 0904729 (herein the "EP publication"). Claim 25 has been canceled. Claims 10 and 22-23 depend directly on amended claims 1 and 19, respectively, and are believed to be allowable for at least the reason that they depend from allowable independent claims. Thus, it is respectfully requested that the rejection of claims 10 and 22-23 under 35 U.S.C. §103 be withdrawn.

Claims 14-15, 18 and 26-29 are rejected as allegedly being obvious over EP 0904729 (the "EP publication") in view of Holowko *et al.* However, claims 14-15, 18 and 29 depend directly or indirectly on amended claim 1. Claim 28 has been canceled. Claims 26 and 27 depend directly on amended claim 19, and are believed to be allowable for at least the reason that they depend from allowable independent claims. Thus, it is respectfully requested that the rejection of claims 14-15, 18, 26-27 and 29 under 35 U.S.C. §103 be withdrawn.

Claims 16 and 24 are rejected as allegedly being obvious over EP 0904729 (the "EP

publication”) in view of Oswin *et al.* However, claims 16 and 24 depend directly on amended claims 1 and 19, respectively, and are believed to be allowable for at least the reason that they depend from allowable independent claims. Thus, it is respectfully requested that the rejection of claims 16 and 24 under 35 U.S.C. §103 be withdrawn.

In addition, MPEP §2141.02 states that “[A] prior art reference must be considered in its entirety, *i.e.*, as a whole, including portions that would lead away from the claimed invention.”¹ [Emphasis added.]

The Examiner indicates that the EP publication teaches the use of spectrophotometry to determine NO while Oswin *et al.* teach measuring breath oxides using an electrochemical cell and that it would have been within the skill of one in the art to modify the EP publication and use the electrochemical cells to gain the indicated advantages by Oswin *et al.* However, the EP publication teaches the use of spectrophotometry to determine NO₂ (see paragraph [0031] while Oswin *et al.* teach the use of an electrochemical cell without ever mentioning NO. Rather, Oswin *et al.* focus on breath ethanol (EtOH) measurements. In dealing with NO measurements in the diagnosis of a condition (*e.g.*, asthma) the skilled artisan would simply not turn to Oswin *et al.* who focus on the measurement of exhaled EtOH (*e.g.*, testing for alcohol consumption). One cannot simply replace one sensor for another. Thus, there is no motivation to combine these reference since the skilled artisan would be faced with entirely different applications.

Claims 13 and 20-21 are rejected as allegedly being obvious over EP 0904729 (the “EP publication”) in view of Birks *et al.* However, claims 13 and 20-21 depend directly on amended claims 1 and 19, respectively, and are believed to be allowable for at least the reason that they depend from allowable independent claims. Thus, it is respectfully requested that the rejection of claims 13 and 20-21 under 35 U.S.C. §103 be withdrawn.

Additionally, the Examiner asserts that it would have been within the skill of the art to modify the EP publication in view of Birks *et al.* and use an NO scrubber on the breath sample prior

¹ *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1083), cert. denied, 469 U.S. 851 (1984).

to analysis to gain the indicated advantages. The Applicants submit that there is no motivation to combine these references because Birks *et al.* measures ozone while the EP publication measures the conversion of NO to NO₂. But even if the skilled artisan would be motivated to combine the EP publication with Birks *et al.* (which is denied) the combination would still not lead to the present invention. Specifically, Birks *et al.* teach a method of measuring the concentration of any chemical species in a gas such as air if that gas reacts with ozone at a sufficient rate to cause a measurable change in the ozone concentration. As indicated above, the EP publication measures the conversion of NO to NO₂. Thus, using the NO scrubber from Birks *et al.* in combination with the EP publication would not lead to the present invention as reflected in the amended claims.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. **514862000700**.

However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

By 

Brigitte A. Hajos

Registration No.: 50,971

MORRISON & FOERSTER LLP

425 Market Street

San Francisco, California 94105

(415) 268-6085